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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,768	10/29/2001	Eric H. Bachrecke	4115-131	3246

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

DAVIS, MINH TAM B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/016,768

Applicant(s)

BAEHRECKE, ERIC H.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 March 1104.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 13, 18, 20-24 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) 13, 18, 21, 23-24, 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 20, 22 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 4-5 and adds new claims 26-33.

Applicant asserts that the new claims include product and methods of use claims, wherein the methods of use claims recite all the limitation of the product claims. Applicant asserts that when the product claims are found allowable, Applicant requests rejoining of the method of use claims.

Since applicant has elected group 2, the polypeptide of SEQ ID NO:1, 2 and 8, for action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the embodiments of claims 29-33 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03. Newly submitted claims 29-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide product as claimed can be used in a materially different process such as for biochemical assay.

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**Accordingly, claims 1-3, 20, 22 and 26-28 are examined in the instant application.**

New claims 29-33 are withdrawn from consideration as being drawn to non-elected invention.

It is noted that any rejoining of the method claims would be considered only at the time of allowance, if the pending claims are allowable.

Claim 26 seems to be free of prior art and is allowable.

#### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT**

Claims 1-3, 20, 22 remain rejected under 35 USC 112, first paragraph, for reasons already of record in paper of 12/11/03.

New claims 27-28 are rejected for the same reasons already of record.

**A. Claims 1-3, 20, 22, 27 are not enabled for a polypeptide that induces cell death in vitro consisting of SEQ ID NO:1 or 2 or a variant thereof.**

Rejection remains because Applicant does not address this issue.

It is noted that SEQ ID NO:1 is only a fragment of full length Drosophila E93 sequence, and that SEQ ID NO:2 is only a fragment of SEQ ID NO:8. Although the full length sequence Drosophila E93 and SEQ ID NO:8, could induce cell death in vitro, there is no indication that their fragments, SEQ ID NO: 1 or 2 alone could induce cell death, in view that protein chemistry is highly unpredictable, and that a change of even a single amino acid could dramatically affect the biological activity of a protein, as taught by Bowie et al, Burgess et al and Lazar et al, all of record, and further in view that it is

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well known in the art that not any fragment of a protein is responsible for the function of a protein.

**B. Claims 20, 28 are not enabled for a variant of SEQ ID NO:2 or 8.**

Applicant asserts that the claims were amended to have the following four parameters:

- 1) At least 90% homology to SEQ ID NO:2.
- 2) A conserved carboxy end region having an amino acid sequence of amino acid residues of 39-53 of SEQ ID NO:2,
- 3) Conservative changes in any amino acid substitutions, and
- 4) induces cell death.

Applicant asserts that determination of homology, and of an amino acid linear sequence is routine in the art. Applicant asserts that conservative substitution is well known in the art. Applicant asserts that one can screen for the variants for inducing cell death.

Applicant's arguments in paper of 03/11/04 have been considered but are found not to be persuasive for the following reasons:

It is noted that there is no indication that the carboxy end region of any length, having amino acid residues 39-53 of SEQ ID NO:2, by itself alone could induce cell death.

It is further noted that the claims reads on a variant of SEQ ID NO:2 having 1) 90% homology to SEQ ID NO:2, 2) a conserved carboxy end region of any length, having amino acid residues 39-53 of SEQ ID NO:2, 3) conserved substitutions, wherein

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said variant could have "any deletion or addition" at any amino acids outside of the conserved carboxy end, and wherein the effect of the deletion or addition on the function of SEQ ID NO:2 is not predictable, in view of the teaching of the art that protein chemistry is highly unpredictable, and that a change of even a single amino acid could dramatically affect the biological activity of a protein, as taught by Bowie et al, Burgess et al and Lazar et al, all of record.

The same reasons set forth above and in previous Office action apply as well to the variant of SEQ ID NO:8 as claimed in claim 28.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

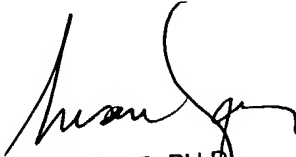
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CHRISTINA CHAN can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER

MINH TAM DAVIS

May 24, 2004